



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Stephen Grimes *et al.*

Art Unit : 1641

Serial No. : 10/813,336

Examiner : Foster, Christine E.

Filed : March 29, 2004

Conf. No. : 5110

Cust. No. : 20985

Title : GASTRIN HORMONE IMMUNOASSAYS

**Mail Stop RCE**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

This Supplemental Information Disclosure Statement is filed with a Request for Continued Examination of the above-captioned application and prior to receipt of an Office Action. Thus, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (4 pages) and copies of the cited non U.S. Patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Provided herewith is a copy of a Written Opinion of the International Searching Authority, issued November 8, 2004, in connection with International Patent Application No. PCT/US2004/009666 (Attorney Docket No. 17118-064WO1/ 2843PC). In the Written

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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman

Opinion, Examiner cites five documents: D1 (US 5607676), D2 (WO 01/77685), D3 (Sugano et al., "Identification and characterization of glycine-extended post-translational processing intermediates of progastrin in porcine stomach", *J. Biol. Chem.* 260(21):11724-117 (1985)), 4) Varro et al., "Gastrin: an analytical review" *Annals of Clinical Biochemistry* 40(5):472-480 (2003), 5) Rahier et al., "Biosynthesis of gastrin. Localization of the precursor and peptide products using electron microscopic-immunogold methods" *Gastroenterology* 92(5):1146-1152 (1987) and 6) Köhler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity", *Nature* 256:495-497 (1975). Documents D1, D2, D3, 4 and 5 have already been made of record in the instant application in Information Disclosure Statements, supplied with Forms PTO-1449, filed April 18, 2005 and March 3, 2006. Document 6 is being made of record in this Supplemental Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited documents.

Applicant also makes known to the Examiner the following pending U.S. Application that has one or more common inventors and/or is commonly owned:

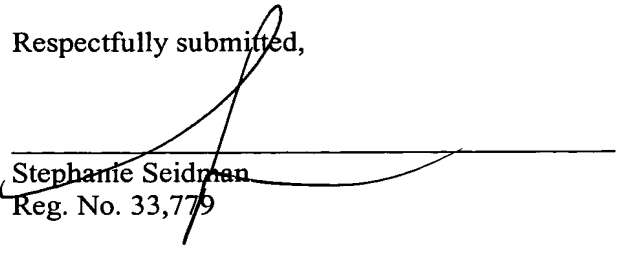
<u>Serial No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
10/762,226	01/20/04	17118-056002/ 2835B
10/235,236	09/04/02	17118-057002/ 2836B
10/323,692	12/19/02	17118-057003/ 2836C
10/098,690	03/15/02	17118-058002/ 2837B
10/829,137	04/21/04	17118-059US2/ 2838BUS
11/252,904	10/18/05	17118-060US3/ 2839CUS
11/360,378	02/22/06	17118-062002/ 2841B
10/192,257	07/09/02	17118-063001/ 2842
11/499,261	08/03/06	17118-064003/ 2843C
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11/489,775	07/20/06	17118-073004/ 2849D
11/492,695	07/25/06	17118-073005/ 2849E
PCT/US2005/10532	03/29/05	17118-064WO2/ 2843BPC
PCT/IB2006/001572	06/13/06	17118-068WO1/ 2847PC

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant : Grimes et al.  
Serial No. : 10/813,336  
Filed : March 29, 2004

Attorney's Docket No.: 17118-064001 / 2843  
Supplemental Information Disclosure Statement

Respectfully submitted,



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Attorney Docket No. 17118-064001 / 2843  
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Sheet 1 of 4

 Patent Application Form PTO-1449  
 (Modified)

 U.S. Department of Commerce  
 Patent and Trademark Office

 Attorney's Docket No.  
 17118-064001 / 2843

 Application No.  
 10/813,336

**List of Patents and Publications for Applicant's  
 Information Disclosure Statement**

 Applicant  
 Grimes et al.

 Filing Date  
 March 29, 2004

 Group Art Unit  
 1641

(37 CFR §1.98(b))

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2002/0095028	7/18/02	Grimes et al.	530	412	3/15/02
	AB	2003/0068326	4/10/03	Gevas et al.	424	185.1	12/6/02
	AC	2003/0086941	5/8/03	Michaeli et al.	424	185.1	9/4/02
	AD	2003/0091574	5/15/03	Gevas et al.	424	155.1	3/22/02
	AE	2004/0001842	1/1/04	Michaeli et al.	424	185.1	12/19/02
	AF	2005/0025770	2/3/05	Gevas et al.	424	155.1	1/20/04
	AG	2005/0169979	8/4/05	Michaeli et al.	424	184.100	1/14/05
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	AI	2006/0039911	2/23/06	Gevas et al.	424	145.1	10/18/05
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	AM	5,688,506	11/18/97	Grimes et al.	424	184.1	1/27/94
	AN	5,843,446	12/1/98	Ladd et al.	424	184.1	6/7/95
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	AQ	6,169,173	1/2/01	Wank	536	23.5	3/10/93
	AR	6,303,123	10/16/01	Grimes et al.	424	184.1	6/7/95
	AS	6,359,114	3/19/02	Grimes et al.	530	344	6/7/95
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	AU	6,565,813	5/20/03	Garyantes	422	102	08/02/00


**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AV	WO 90/08774	8/9/1990	PCT				
	AW	WO 95/13297	5/18/1995	PCT				
	AX	WO 98/51337	11/19/98	PCT				

Examiner Signature

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)  <b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office 	Attorney's Docket No. 17118-064001 / 2843	Application No. 10/813,336
	Applicant Grimes et al.		
	Filing Date March 29, 2004	Group Art Unit 1641	

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AY	WO 99/59612	11/25/99	PCT				
	AZ	WO 99/59628	11/25/99	PCT				
	BA	WO 02/076499	10/03/02	PCT				
	BB	WO 06/008649	1/26/06	PCT				
	BC	WO 06/016275	2/16/06	PCT				

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	BD	Abrahm et al., "Development and evaluation of a high affinity species and region specific monoclonal antibody to human gastrin," <i>Gastroenterology</i> , 86(5(2)):1012, (1984).
	BE	Aphton Biopharma BIO2005 Presentation, June 19-22, Philadelphia, PA (2005), 26 pages
	BF	Ausubel, ed., "Current Protocols in Molecular Biology," John Wiley & Sons, New York, pp 11.15.1-11.15.4. (1990).
	BG	Blackmore et al. "Autocrine growth stimulation of human renal Wilms' tumour G401 cells by a gastrin-like peptide," <i>International Journal of Cancer</i> , 57:385-391, (1994).
	BH	Caplin et al., "Serum gastrin levels and identification of CCK-B-gastrin receptor following partial hepatectomy for liver tumours in man," <i>Gastroenterology</i> , 110(4 suppl.) A1162, (1996).
	BI	Caplin et al., "Demonstration of new sites of expression of the CCK-B/gastrin receptor in pancreatic acinar AR42J cells using immunoelectron microscopy," <i>Regulatory Peptides</i> , 84(1-3):81-89, (1999).
	BJ	Caplin et al., "Effect of gastrin and anti-gastrin antibodies on proliferation of hepatocyte cell lines," <i>Digestive Diseases and Sciences</i> , 46(7):1356-1366, (2001).
	BK	Ciccotosto et al., "Expression, processing, and secretion of gastrin in patients with colorectal carcinoma," <i>Gastroenterology</i> , 109(4):1142-1153, (1995).
	BL	"Gastrin 17 vaccine--Aphton: Anti-gastrin 17 immunogen, G17DT," <i>Biodrugs</i> 17(3):223-225 (2003)
	BM	Gocyk et al., "Helicobacter pylori, gastrin and cyclooxygenase-2 in lung cancer," <i>Med. Sci. Monit.</i> 6(6):1085-1092 (2000)
	BN	Halter et al., "Evaluation of a monoclonal anti-gastrin antibody as a tool for immunoneutralization of gastrin during omeprazole treatment in the rat", <i>Gastroenterology</i> 96(5) part 2:A194 (1989)
	BO	Harris et al., "An antiapoptotic role for gastrin and the gastrin/CCK-2 receptor in Barrett's esophagus," <i>Cancer Res.</i> 64(6):1915-1919 (2004)
	BP	Helander et al., "Immunohistochemical localization of gastrin/CCK-B receptors in the dog and guinea-pig stomach," <i>Acta Physiologica Scandinavica</i> , 159:(4)313-320, (1997).
	BQ	Herget et al., "Cholecystokinin stimulates Ca <sup>2+</sup> mobilization and clonal growth in small cell lung cancer through CCKA and CCKB/gastrin receptors," <i>Annals of the New York Academy of Sciences</i> , 713:283-297, (1994).
	BR	Janeway et al. "Immunobiology: the immune system in health and disease", Fourth Edition, 1999, Elsevier Science Ltd, Garland Publishing, p544

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	Applicant Grimes et al.		
	Filing Date March 29, 2004	Group Art Unit 1641	

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	BS	Joshi et al., "Gastrin and Colon Cancer: a unifying hypothesis" <i>Digestive Diseases</i> 14:334-344 (1996)
	BT	Kohler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity", <i>Nature</i> 256:495-497 (1975)
	BU	McWilliams et al., "Antibodies raised against the extracellular tail of the CCKB/gastrin receptor inhibit gastrin-stimulated signaling," <i>Regulatory Peptides</i> , 99(2-3):157-161, (2001).
	BV	Mishell et al., "Selected Methods in Cellular Immunology" (Chapter 17: Immunoglobulin Producing Hybrid Cell Lines), Freeman and Co., San Francisco, 1980)
	BW	Mulholland et al., "Elevated Gastric Acid Secretion in Patients with Barrett's Metaplastic Epithelium" <i>Digestive Diseases and Sciences</i> , 34(9):1329-1334, (1989).
	BX	Smith et al., "Characterization of the CCK-C (cancer) receptor in human pancreatic cancer" <i>Int. J. Mol. Medicine</i> 10(6):689-694 (2002)
	BY	Smith et al., "Gastrin may have an autocrine/paracrine role in Barrett's oesophagus and oesophageal adenocarcinoma," <i>British Journal of Surgery</i> , 84:706-707, (1997).
	BZ	Tarasova et al., "Anti-peptide antibodies specific for the gastrin-cholecystokinin-B receptor," <i>Letters in Peptide Science</i> , 1:221-228, (1995).
	CA	Tarasova et al., "Endocytosis of gastrin in cancer cells expressing gastrin/CCK-B receptor" <i>Cell and Tissue Research</i> , 287:325-333 (1997)
	CB	Thorndyke, "Identification and localization of material with gastrin-like immunoreactivity in the neutral ganglion of a photochordate, <i>Ciona intestinalis</i> ." <i>Regulatory Peptides</i> 16:269-279 (1986)
	CC	Watson et al., "Antibodies targeting the amino terminal portion of the human CCKB/gastrin receptor inhibit the liver invasion of a human colonic tumor," <i>Gastroenterology</i> 114(4 Part 2): A701 (Abstract # G2899) (April 15, 1998)
	CD	Watson et al., "Effect of gastrin neutralization on the progression of the adenoma:carcinoma sequence in the Min mouse model of familial adenomatous polyposis," <i>Gastroenterology</i> 114(Supplement 1): A701 (Abstract #G2900) (April 15, 1998)
	CE	Watson <i>et al.</i> , "Growth-promoting action of gastrin on human colonic and gastric tumour cells cultured in vitro" <i>Br. J. Surg.</i> 75(4):342-345 (1988)
	CF	Watson et al., "Inhibitory effects of the gastrin receptor antagonist (L-365,260) on gastrointestinal tumor cells," <i>Cancer</i> , 68:1255-1260, (1991).
	CG	Watson <i>et al.</i> , "Anti-gastrin antibodies raised by gastrimmune inhibit growth of colorectal tumor AP5" <i>Int. J. Cancer</i> , 61(2):233-240 (1995)
	CH	Watson et al., "Expression of gastrin-CCKB receptor isoforms in gastrointestinal tumor cells: Relationship to gastrin secretion," <i>Proceedings of the American Association for Cancer Research Annual Meeting</i> , 38(0):116 (Abstract 773), (1997).
	CI	Watson et al., "Antiserum raised against an epitope of the cholecystokinin B/gastrin receptor inhibits hepatic invasion of a human colon tumor," <i>Cancer Research</i> , 60(20):5902-5907, (2000).
	CJ	Watson et al., "Antibodies raised by gastrimmune inhibit the spontaneous metastasis of a human colorectal tumour AP5LV," <i>European Journal of Cancer</i> , 35(8):1286-1291, (1999).
	CK	Watson et al., "Antibodies targeting the Amino Terminal portion of the Human CCKB/gastrin receptor inhibit the liver invasion of a human colonic tumour," <i>Research Presentation, Digestive Disease Week, American Gastroenterological Association</i> (1998), 17 slides

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<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>					
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	CL	Watson et al., "Inhibition of gastrin-stimulated growth of gastrointestinal tumour cells by octreotide and the gastrin/cholecystokinin receptor antagonists, proglumide and lorglumide," European Journal of Cancer, 28A(8-9):1462-1467, (1992).			
	CM	Watson et al., "The in vitro growth response of primary human colorectal and gastric cancer cells to gastrin," International Journal of Cancer, 43:692-696, (1989).			
	CN	Watson et al., "Therapeutic effect of the gastrin receptor antagonist, CR2093 on gastrointestinal tumour cell growth," British Journal of Cancer, 65(6):879-883, (1992).			

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